



DEPARTMENT OF HEALTH AND HUMAN SERVICES

TELECONFERENCE MEMORANDUM

Public Health Service
Food and Drug Administration
Center for Biologics Evaluation and Research

Date\Time: December 5, 2006 \ 2:15 pm

CBER

Representative: Lori Tull

Sponsor's

Representative: Elizabeth Smith

STN : 125197/0

Subject: General questions and advisory committee date

Discussion:

Ms. Smith asked if an acknowledgement letter had been sent out for the BLA. I responded that the letter had been signed and was on it's way to Dendreon by mail.

I informed Ms. Smith that OCTGT would be discussing the BLA submission at the March 29 and 30, 2007 advisory committee meeting. I told her that Ms. Gail Dapolito would contact her regarding the deadlines for submitting a package.

Ms. Smith asked if there was any feedback regarding the imaging submission. I told her that there was no feedback at this time.

The call ended.

OCTGT:IOD:Tull:12/5/06

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